

REMARKS

In an Office Action dated March 22, 2002, the Examiner rejected claims 1-6, 9-25, 28, and 31 and indicated the allowability of the remaining claims 7, 8, 26, 27, 29, 30, and 32. Further, the drawings were objected to for various informalities. In response, Applicant files the present Reply with Amendment and Remarks. Entry and consideration hereof are respectfully requested.

The Examiner's particular objections and rejections are now addressed in turn.

Claims 11-17, 31, and 32 are objected to on informal grounds. Namely, the dependency of claims 31 and 32 is improper and claim 11 includes a typographical error. Herein, claims 11, 31, and 32 are amended to address the Examiner's concerns. Thus, the objections are overcome; reconsideration and withdrawal thereof are respectfully requested.

The drawings are objected to by the Draftsperson as including improper margins, poor line quality, and illegible reference characters. Replacement drawings in which all of the Draftsperson's concerns are addressed, are submitted by separate letter. Thus, the drawing objections are correspondingly overcome; reconsideration and withdrawal thereof are respectfully requested.

Claim 28 and 31 are rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,799,658 to Falco (hereinafter, "Falco"). However, Applicants respectfully submit that Falco fails to teach, or even suggest, all of the claimed limitations and thus the outstanding novelty rejections are improper and may not be maintained.

Claim 28 recites a mold for forming a foam earplug comprising, *inter alia*, an upper mold portion including an upper cavity and a means for venting a gas during a rising of the foam. As will be shown, at least this limitation is not disclosed by Falco.

Falco generally teaches a hearing protective device comprising a foam and a porous component and a method of manufacture thereof. In Figures 4-6, the reference discloses a two-piece mold 100 for practicing the method of manufacture. Col. 7, lines 18-40. The mold 100 includes a bottom 110 and a top 120 with cavities 112 formed in the bottom 110 and corresponding cavities 122 formed in the top 120. *Id.* A mold insert 130 is placed in each bottom cavity 112 and a cap member 140 is placed in each upper cavity 122. *Id.* The cap member 140 seals with the insert 130 during foaming. *Id.*

In use, a porous plastic component is placed into an opening 142 of the cap member 140 and a foam or foamable mixture is introduced into the closed mold 100 and caused to rise. *Id.*, and col. 6, lines 53-67. “No vent channels need be present in mold insert 130 or cap member 140 because the porous stem acts as a mold vent during the manufacturing process.” Col. 7, lines 34-38.

As mentioned above, Applicants’ claim 28 recites *an upper mold portion including a means for venting a gas*. Falco expressly teaches that neither the top 120 of the mold 100, nor the upper cavities 122, nor the top member 140 placed therein include a means for venting a gas. Instead, venting is intrinsically performed in Falco by the stem component which is inserted into the mold 100 to be bonded with the foam, because the stem component is porous in nature. That is, venting in Falco is not performed by the mold 100 nor by any part or portion thereof. Instead, the stem of the earplug being formed in the mold 100 allows venting.

Clearly, Falco does not teach, or even suggest, an upper mold portion including a means for venting a gas, as recited by claim 28. Thus, the reference does not anticipate the claim. Reconsideration and withdrawal of the outstanding §102 rejection of claim 28 is respectfully requested. Claim 28 is not further rejected or objected to, thus the claim is allowable to Applicants.

Claim 31, as amended herein, depends directly upon allowable claim 28 and is thus correspondingly allowable; reconsideration and withdrawal of the relevant anticipation rejection is requested.

Claims 1-3, 5, 6, 9-13, 15-20, and 22-25 are rejected under 35 U.S.C. 103(a) as being obvious over Falco in view of French Patent No. 2,230,336 to ENVAC ESTABLISHMENT (hereinafter, “Envac”). Here, Applicants respectfully assert that the relied-upon references, as combined by the Examiner, fail to satisfy all of the requirements of *prima facie* obviousness.

Of course, to establish a *prima facie* case of obviousness, three basic criteria must be met: (1) there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings; (2) there must be a reasonable expectation of success; and (3) the prior art reference(s) must teach or suggest all the claim limitations. *In re Fine*, 5 U.S.P.Q.2d 1596, 1598 (Fed. Cir. 1988); *In Re Wilson*, 165 U.S.P.Q. 494, 496 (C.C.P.A. 1970); *Amgen v. Chugai Pharmaceuticals Co.*, 927 U.S.P.Q.2d 1016, 1023 (Fed. Cir. 1996).

As will be shown herein, the Examiner’s combination of the Falco and Envac references fail to satisfy at least the first of these enumerated requirements. That is, there is no suggestion or motivation to combine and modify the references as proposed by the Examiner.

As mentioned above, Falco generally teaches a hearing protective device comprising a foam and a porous component and a method of manufacture thereof. More specifically, an earplug 10 is shown in Figures 2 and 3A as including a foam 12 mechanically bonded to a porous component 14. Col. 4, lines 34-59. The component 14 includes an embedded portion 18 disposed within the foam 12 and a handle portion 16 extending freely from the foam 12 to an exterior of the earplug 10. *Id.* Notably, the stem component 14 is composed of a porous material which acts a mold vent during formation

of the earplug 10. *Id.* That is, during manufacture, the porous component 14 is placed within a mold such that the handle portion 16 extends from the mold. The foam 12 is then formed within the mold such that the foam 12 penetrates the porous stem 14 at the embedded portion 18 and bonds therewith. *Id.* Entrapped air within the mold may pass through the porous stem 14 as the foam expands and then bonds with the stem 14. *Id.* That is, the porosity of the stem 14 allows entrapped air to pass from the interior of the mold through the embedded portion 18 to the handle portion 16 and thus to an exterior of the earplug. Thus, necessarily, the handle portion 16 of the stem 14 may not be encapsulated within the foam 12 but instead, to facilitate venting, must extend outside of the foam 12 and hence outside of the mold used to manufacture the earplug 10.

As clear from the preceding discussion and as conceded by the Examiner, Falco does not expressly teach a component disposed at least partially within a foam insertable portion *and at least partially within a foam handle portion*, as recited by claim 1. See, Office Action, page 5, lines 6-10. Applicants further submit that Falco does not even suggest this limitation. This is because, as mentioned, Falco requires that the handle portion 16 of its stem component 14 extend freely from the foam 12 to an exterior of the earplug 10. This is necessary to allow the stem 14 of Falco to perform its venting function. See e.g., col. 4, lines 28-59. To nest the handle portion 16 of the stem 14 within the foam 12, the handle portion 16 would have to be located within the mold during manufacture of the Falco earplug, thus the venting feature of the component 14 would be negated.

Therefore, not only does Falco not disclose a component nestable in both in an insertable portion and a handle portion, as required by Applicants' claim 1, but the reference directly teaches away from such limitation.

Turning to Envac, an earplug is disclosed consisting of a ball or spherical body 1 having a pin 3 attached thereto and extending therefrom, as shown in Figures 1-2. See, Page 2, lines 21-22 and page 3, lines 8-23 of the English Translation of Envac attached hereto at ANNEX. Figure 3 of Envac shows the pin 3 completely coated by polymer

material that is molded to form a single part with the spherical body 1. Page 3, line 28 – page 4, line 2.

The Examiner contends that it would have been obvious to one of ordinary skill in the art to have the features of Envac in the device of Falco to make it more soft to the touch. Office Action, page 5, lines 6-10.

However, to combine Envac and Falco as suggested would render Falco unsatisfactory for its intended purpose. That is, encapsulating the stem component 14 of Falco as shown in Figure 3 of Envac would negate Falco's porous stem venting feature. Moreover, without this venting feature, it is likely that the foam 12 of Falco would not properly and/or fully form in the mold 100. Thus, since the proposed modification would not be possible and, even if possible, would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984). Accordingly, for at least this reason, *prima facie* obviousness of claim 1 is not found with respect to Falco and Envac.

Accordingly, the outstanding obviousness rejection of claim 1 is improper and may not be maintained; reconsideration and withdrawal thereof is respectfully requested. Claim 1 is not further objected or rejected and is thus allowable to Applicants.

As mentioned, claims 2, 3, 5, 6, 9, and 10 are also rejected as being obvious over Falco and Envac. However, these claims variously depend from allowable claim 1 and are thus correspondingly allowable; reconsideration and withdrawal of the relevant rejections is respectfully requested.

Independent claim 11, also rejected as obvious over Falco and Envac, recites *inter alia* a set of a first and second earplugs each including a component disposed at least partially within a foam insertable portion and at least partially within a foam handle portion. As discussed above with respect to claim 1, to modify Falco by way of Envac to form these limitations of claim 11 would be to render Falco unsatisfactory for its intended

purpose. Thus, there exists no suggestion or motivation to combine and modify the references as proposed by the Examiner. Accordingly, claim 11 is not *prima facie* obvious; reconsideration and withdrawal of the outstanding rejection is respectfully requested. Claim 11 is not further rejected and is thus allowable to Applicants.

Claims 12, 13, and 15-17 are similarly rejected under §103 in view of Falco and Envac. However, these claims variously depend from allowable claim 11 and are thus correspondingly allowable; reconsideration and withdrawal of the relevant rejections is respectfully requested.

Claim 18, also rejected as obvious over Falco and Envac, recites a method of making an earplug comprising, *inter alia*, causing foam to rise about a component such that the component is bonded and nested at least partially within a foam insertable portion and at least partially within a foam handle portion. Accordingly, for at least the reasons set forth above with respect to claims 1 and 11, there exists no suggestion or motivation to modify and combine Falco and Envac to form these claim limitations. Thus, *prima facie* obviousness is not established; reconsideration and withdrawal of the outstanding rejection of claim 18 is respectfully requested. Claim 18 is not further objected or rejected and is thus allowable to Applicants.

Claims 19, 20, and 22-25, as mentioned, are rejected as obvious over Falco and Envac. These claims, however, variously depend from allowable claim 18 and are thus correspondingly allowable; reconsideration and withdrawal of the rejections is requested.

Thus, in sum, all of claims 1-3, 5, 6, 9-13, 15-20, 22-25 are non-obvious with respect to the Falco and Envac references for at least the reasons set forth herein.

Claims 4, 14, and 21 are rejected as being obvious under §103(a) in view of Falco and Envac as combined with U.S. Patent No. 2,804072 to Genzer. These claims, however, variously depend from allowable independent claims 1, 11, and 18 and are thus correspondingly allowable; reconsideration and withdrawal of the rejections is requested.

Accordingly, all of the Examiner's objections and rejections are herein addressed and overcome.

Claims 26, 27, and 32 are indicated by the Examiner in the Action as being allowable if amended to include all of the limitations of the base and intervening claims. Herein, claim 26 is amended to include all of the limitations of base claim 18 and intervening claim 23; claim 27 is amended to include all of the limitations of base claim 18 and intervening claims 26 and 23; and claim 32 is amended to include all of the limitations of base claim 18 and intervening claims 23, 26, and 27. Thus, claims 26, 27, and 32 are now allowable.

New claims 33-43 are herein added. New claim 33 includes many of the limitations of original claims 1 and 6 and further recites the vent comprising a tortuous path. Support for this amendment is found throughout the originally filed application, for example at page 13, lines 17-20. New claims 34-36 are similar to original claims 7-8 and further define the tortuous path. New claim 37 includes many of the limitations of original claims 28-29 and further recites the means for venting including a tortuous path. Support for the amendment is found expressly at page 13, lines 17-20 and implicitly in the figures and related descriptions of the venting means. New claims 38-40 further describe the tortuous path of claim 37. Finally, new claims 41-43 further define the tortuous path of claims 33 and 37, respectively. These newly added claims 33-43 contain limitations not taught or suggested by the cited references. Consideration and allowance of these claims is respectfully requested.

No new matter is added by way of the present Amendment and Remarks.

As set forth in detail herein, claims 1-43 are now allowable over the cited art. Withdrawal of all rejections and prompt issuance of a Notice of Allowance is respectfully requested.

The Examiner is invited to contact Applicants' attorneys at the below-listed phone number regarding this Response or otherwise concerning the present application.

If there are any charges due with respect to this Amendment or otherwise, please charge them to Deposit Account No. 06-1130 maintained by Applicants' attorneys.

Respectfully submitted,
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ANNEX

The present invention relates to an auditory protection unit to be inserted into the auditory canal in order to plug it. Means for protecting the ear from noise levels up to 100 decibels using auditory protection units of various kinds, which may be composed of fibrous materials such as cotton wadding and fiberglass, possibly impregnated with a wax capable of plastic deformation, 5 or composed of hollow parts made of rubber equipped with at least one flange in order to seal the auditory canal, are known. Unfortunately, these known protection means involve various disadvantages. Hence, auditory protection units made of fibrous material must be adapted to fit the shape and size of the user's auditory canal; that is, they must be adapted to fit each individual. This observation is especially valid for units made of wax-impregnated fibers.

10 Moreover, it is often necessary to divide commercially available units into smaller pieces, which, as is true for the need to sculpt the unit to fit a desired conformation, is harmful to hygiene. Additionally, these known units do not always yield the same level of sealing, meaning that their effectiveness is not reproducible, since the user's skill in handling the unit is a determining factor in its effectiveness. Further, many users experience auditory canal irritation due to auditory 15 protection units made of fibrous material. For a unit made up of an elongated rubber body and equipped with a flange, multidimensional production is called for because the likelihood that this type of rubber body can adapt to various auditory canal sizes is very low, and because the seal is provided solely by the flange. This type of unit is also relatively expensive and is therefore intended to be used several times, which is not hygienic. In order to insert this unit, the user must 20 push it into the auditory canal while turning it, which is often unpleasant. This insert must also be performed with care and skill, meaning that the user must go through a training period in order to get all of the use out of the unit that he/she might normally expect.

The goal of the invention is therefore to make an auditory protection unit that is free of the disadvantages associated with known units; that is inexpensive enough for one-time use, 25 which is necessary in order to meet the highest level of hygienic conditions; and that, additionally, ensures the same protection effectiveness during each use regardless of the user's skill level. In order to obtain these results, the auditory protection unit of the invention, which is to be inserted into the auditory canal, plugging it, is characterized by including a body that is roughly round in all of its sections, composed of a polymer material enclosing numerous gas

inclusions, and having an impermeable surface along with a plug element attached to the part that enables it to be handled.

In a preferred form, the plug element is composed of an elongated pin made of a material that is harder than the round body and that extends into the body made of polymer material from 5 one side of this body until it reaches the region of this body that is located beyond its maximum cross section, as seen from the free end of the pin, and that is attached to the inside of the body by a chemical bond. Thanks to this characteristic, the body made of polymer material is not pushed into the auditory canal but is instead inserted while undergoing traction. Since the point where the force is applied is located forward of the maximum cross section of the body, which 10 has been deformed by the insertion; this makes the insertion considerably easier and much less unpleasant for the user, and offers the additional advantage of making it possible to insert the protection unit to a sufficient depth for it to be effective.

Other characteristics and advantages of the invention will emerge in the following description, which refers to the attached drawings, provided solely by way of example, wherein:

15 - Fig. 1 is a cross-section view of an initial embodiment of an auditory protection unit including a body that is round in all of its sections and an elongated pin;

- Fig. 2 shows the protection unit of Fig. 1 when it is being inserted into the auditory canal; and

20 - figures 3, 4, and 5 show other embodiments of an auditory protection unit according to the invention.

The auditory protection unit of figures 1 and 2 includes a ball or spherical body 1 made of polymer material containing a large number of gaseous inclusions 2. In this embodiment, the polymer material forms a reticular volume of roughly 1 cm^3 that has open pores and closed cells; the individual space of the pores and of the cells is less than 1 mm^3 . The ratio of the number of 25 open pores to the number of closed cells may vary widely, roughly from 0 to 10; the apparent density may vary from 0.2 to 15 g/cm^3 ; the compression strength may vary from 25 to 90% compression, measured after a 10 minute period of static compression of a cylindrical test piece

25 mm in diameter and 25 mm tall, subjected to a pressure of 306 g/cm² exerted parallel to the test piece's revolution axis. The permanent deformation of this type of test piece after a period of 22 hours, during which it has been compressed to one-half its initial height at 23°C, measured 30 minutes after the compression force has been stopped, varies from 5 to 40%. The ball 1 has an
5 essentially impermeable outer surface 11, which facilitates insertion into the auditory canal. This surface, which envelops the ball essentially like a skin, may include lubricants and/or substances able to prevent any irritation to the skin in the auditory canal due to the ball.

In the embodiment shown in figures 1 and 2, the plug element is composed of an elongated pin 3 made of a material that is harder or more resistant than the material making up
10 the ball 1 and that extends into the ball from one of the latter's sides up to the area 6 of this ball 1 that is located beyond its maximum cross section 5, seen from the free end of the pin. Since the point where force is applied to the ball 1 is therefore located forward of this maximum cross section, this ball is not pushed from the rear when it is inserted into the auditory canal but is inserted while it undergoes tractive force applied to the front, which facilitates insertion into the
15 auditory canal and prevents this insertion from feeling unpleasant. Additionally, thanks to this approach to the invention, the protection unit can be inserted deeply and effectively enough without the user resisting it consciously or unconsciously. Therefore, as can be seen in Fig. 2, when the pin 3 is placed inside the auditory canal 8 in the direction of the arrow 9, it exerts, on the contact points between the ball 1 and the wall 7 of the auditory canal, forces 10 that create a
20 tractive effect, such that the ball 1 is not compressed but rather becomes elongated. Thanks to the spherical shape of the body 1 made of polymer material, the sealing effect established with the auditory canal wall is independent of the orientation of this ball in this canal, so the same protective effect continues to be obtained regardless of the skill with which the device is handled.

The polymer material of the ball 1 may be, for example, a polyurethane foam or a
25 mixture of polyvinyl chloride and plasticizer. The manufacture of the mixture and the inflation of the foam are performed using known methods. The elongated pin 3, used to insert the ball of polymer material into the auditory canal and to remove it from this canal, must be harder than the ball 1 and may be made of paper, cardboard, or wood. Additionally, this pin may be completely coated by polymer material that is molded to form a single part with the ball 1, as in the example
30 shown in Fig. 3.

Moreover, the ball 1 and the pin 3 may be made of identical or similar materials, in which case the pin may be, for example, made of polyvinyl chloride that is harder than that making up the ball 1. By using a pin made of polymer material, a resistant chemical bond between the pin and the ball over the entire contact surface between the two elements is obtained without special handling or requiring the use of an adhesive. Fig. 4 shows a hearing protection unit that follows this approach, wherein the pin 13 is made of a material that is identical or similar to that of the ball 1, but harder. The ball 1 of this type of device preferably has a diameter of $12\text{ mm} \pm 2\text{ mm}$ and is composed of a plasticized polyvinyl chloride, to which a solid foaming agent is added. A pin 13 is driven into this ball up to an area inside it that is located beyond its maximum cross section. The pin is roughly 30 mm long and about 3.5 mm in diameter, and is composed of polyvinyl chloride that is less plasticized and free of foaming agent.

In order to manufacture this hearing protection unit, we proceed as follows: first, the pin, manufactured separately using a known method – extrusion, for example – is set inside a metal mold with a spherical mold printing, and about 0.4 g of a mixture composed of 25 to 50% by weight of polyvinyl chloride powder, 45 to 74% by weight of plasticizer, and 1 to 5% by weight of foaming agent is placed inside the mold. If necessary, the mixture may also contain other additives. After closing the mold, the latter is brought to a temperature from 130 to 200°C; this processing yields a spherical ball 1 that is made of a polymer reticular volume including numerous small gas inclusions and that is firmly bound to the pin. At the same time, the protection device is sterilized by the high temperature. This manufacturing method also yields a nearly impermeable surface layer that envelops the ball and makes it easier to insert into the auditory canal. Thanks to the reduction in the polymer material's apparent density due to the gas inclusions, this device weighs less than 1 gram. Costs for materials are very low, so using this device is still inexpensive when this device must be thrown away after a single use, as hygiene concerns make advisable.

Lastly, Fig. 5 shows another embodiment wherein the pin is replaced by a cord 23; here, the cord can only be used to remove the protection device and cannot facilitate its insertion.

CLAIMS

1. Hearing protection unit designed to be inserted into an auditory canal, wherein it includes a roughly spherical body (1) composed of a polymer material enclosing a large number of gas inclusions (2), and that has an almost totally impermeable outer surface (11), and a plug element (3), preferably attached to the body by a chemical bond, used to facilitate handling of this body.
5
2. Unit according to Claim 1, wherein the plug element is composed of an elongated pin (3) that is harder than the nearly-spherical body (1), and that extends into the body (1) from one of the sides of this body up to an area (6) of the body that is located beyond its maximum cross section (5), as seen from the free end of the pin.
- 10 3. Unit according to Claim 2, wherein the round body (1) and the elongated pin (3) are composed of an identical or similar polymer material, with only the body enclosing gas inclusions (2).
4. Unit according to either of claims 2 or 3, wherein the pin (3) driven into the body (1) is firmly attached to the body over its entire surface of contact with this body, specifically by a chemical bond.
- 15 5. Unit according to Claim 2, wherein the elongated pin is made of paper, cardboard, or wood.
6. Unit according to Claim 5, wherein the pin driven into the round body is completely covered by a layer of polymer material that is molded along with the body to form a single part.
7. Unit according to Claim 1, wherein the polymer material of the round body (1) is polyurethane foam.
- 20 8. Unit according to Claim 1, wherein the polymer material of the round body (1) is composed of a mixture of polyvinyl chloride and plasticizer.
9. Unit according to Claim 1, wherein the body (1) is spherical in shape and has a diameter ranging from 9 to 15 mm.
- 25 10. Unit according to Claim 1, wherein the plug element is composed of a cord (23) anchored inside the body (1).

11. Unit according to claims 1 and 7 or 1 through 8, wherein it is sterilized when the heat needed to form the polymer material foam is added, and packaged while in this condition.